DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 19 1988

#27

Re: Sensor® Model Kelvin® 500 Unipolar Pulse Generator, and Model K Unipolar Sensing Lead Sensor Model Kelvin 500 Pulse Generator. Model K Endocardial Lead, Model 5000 Transceiver, and Model 50 Lead Tester

Docket No. 88E-0269

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Quigg:

This is in regard to the application for patent term extension for U.S. Patent No. 4,543,954, filed by Purdue Research Foundation under 35 U.S.C. 156 et seq.

The medical device claimed by the patent is the Sensor® Model Kelvin® 500 Unipolar Pulse Generator, and Model K Unipolar Sensing Lead Sensor Model Kelvin 500 Pulse Generator, Model K Endocardial Lead, Model 5000 Transceiver, and Model 50 Lead Tester (Sensor Model Kelvin 500), exercise cardiac pacemaker.

We have reviewed the Food and Drug Administration's Official records and have determined the regulatory review period for the Sensor Model Kelvin 500. The total length of the review period for Sensor Model Kelvin 500 is 696 days. Of this time, 572 occurred during the testing phase of the regulatory review period and 124 occurred during the approval phase. The periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: June 5, 1986. FDA has verified the applicant's claim that June 5, 1986 is the date a clinical investigation was begun.

2. The date the application was initially submitted with respect to the device under subsection 515 of the Federal Food, Drug, and Cosmetic Act: December 28, 1987.

The applicant claims September 4, 1987 as the date that the product marketing application for the device (PMA 870054) was initially submitted. However, FDA records indicate that PMA 870054 was not sufficiently complete to permit substantive review until December 28, 1987.

3. The date the application was approved: April 29, 1988. FDA has verified the applicant's claim that PMA 870054 was approved on April 29, 1988.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Clifford W. Browning
Woodward, Emhardt, Naughton,
Moriarty & McNett
One Indiana Square
Suite 2000
Indianapolis, Indiana 46204